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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/657,420   | 09/08/2003  | Jose E. Lizardi      | 022956-0238         | 9019             |
| 21125  | 7590        | 03/31/2005           | EXAMINER            |                  |
| NUTTER MCCLENNEN & FISH LLP<br>WORLD TRADE CENTER WEST<br>155 SEAPORT BOULEVARD<br>BOSTON, MA 02210-2604 |             |                      | MENDOZA, MICHAEL G  |                  |
|  |             | ART UNIT             | PAPER NUMBER        | 3731             |

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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|   |                        |                     |  |
|---|------------------------|---------------------|--|
| <b>SUPPLEMENTAL<br/>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|   | 10/657,420             | LIZARDI, JOSE E.    |  |
|   | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|   | Michael G. Mendoza     | 3731                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 08 September 2003.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 70-85 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 70-85 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)          |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Information Disclosure Statement***

1. The information disclosure statement filed 30 January 2004 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

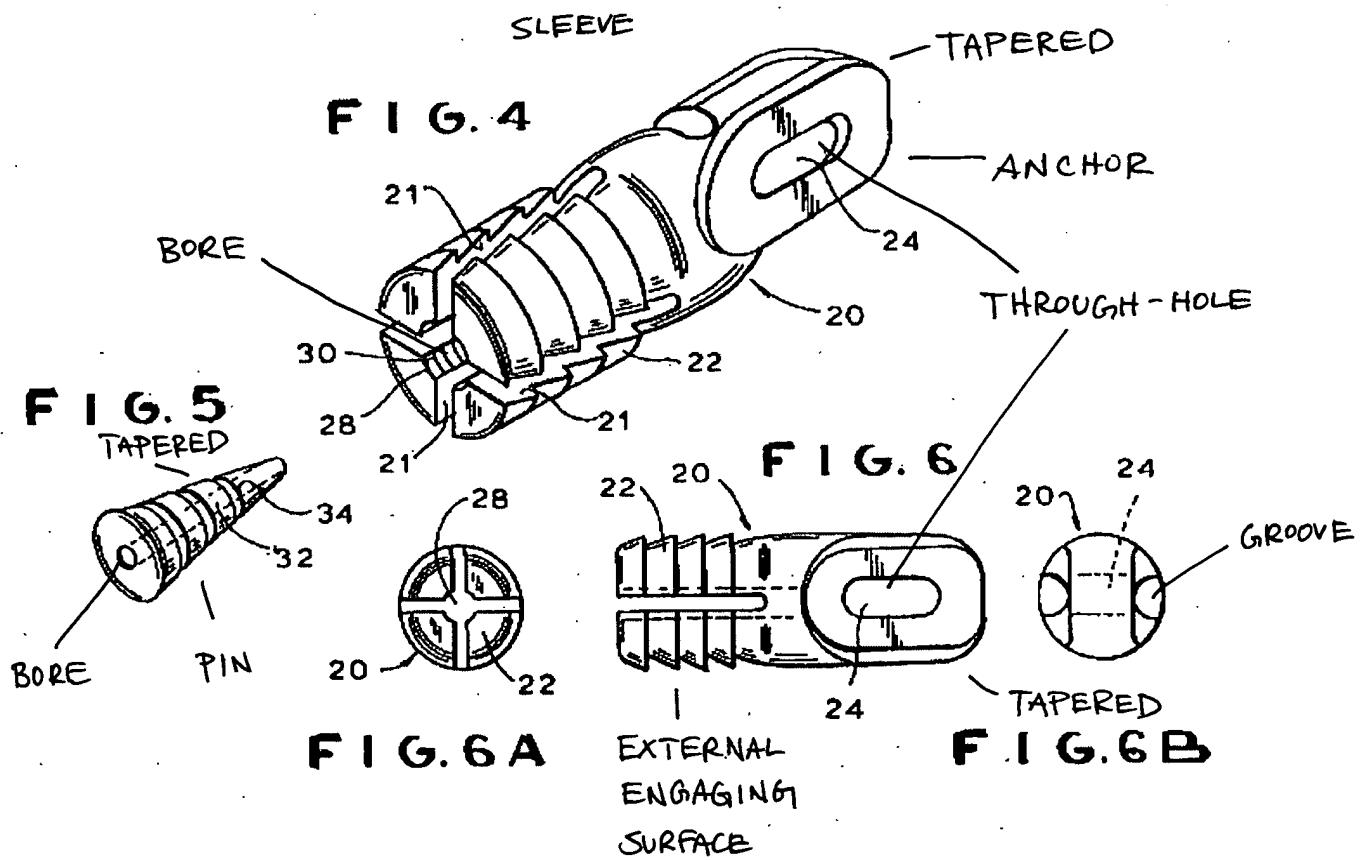
A person shall be entitled to a patent unless –

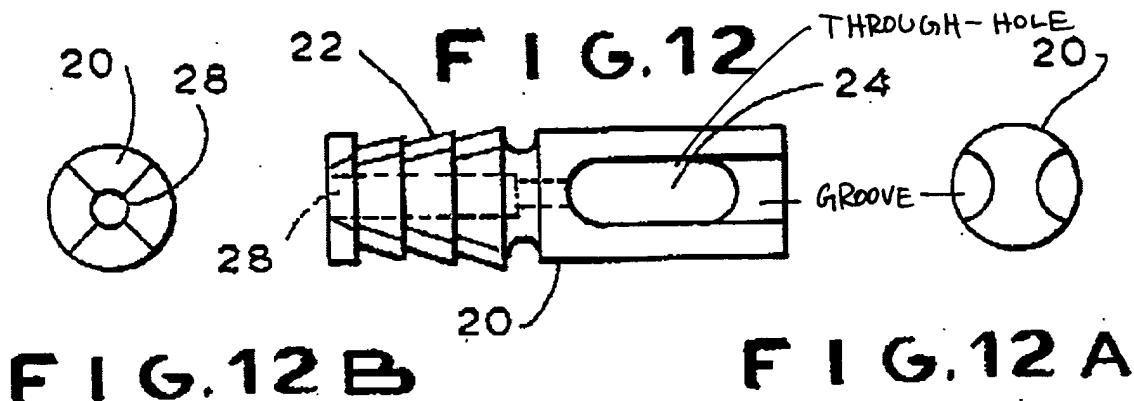
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 70-79 and 81 are rejected under 35 U.S.C. 102(b) as being anticipated by Li 5707395.

4. Li teaches a radially expandable suture anchor including a bore; a suture engaging tip having a suture thread-engaging groove; an expander pin; the suture

anchor including a through-hole extending therethrough in a direction transverse to a longitudinal axis of the anchor; wherein the suture engaging tip is tapered (as shown in figs 1-3); wherein the suture anchor is comprised of an expandable sleeve in engagement with the suture engaging tip; wherein the expandable sleeve and the suture engaging tip are threadingly engaged (30 & 34); wherein the suture anchor includes an external surface feature for engaging bone; wherein the external surface feature is selected from the group consisting of ridges, wedges, and fins; wherein the expander pin includes a tool-engaging bore extending from a proximal end thereof; wherein the expander pin includes a surface feature effective to assist in the radial expansion of the sleeve (conical shape); and wherein the anchor further includes a pair of longitudinally extending slits; and wherein the expander pin is tapered.





*Claim Rejections - 35 USC § 103*

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
6. Claim 80 is rejected under 35 U.S.C. 103(a) as being unpatentable over Li in view of Tovey et al. 5928244.
7. Li teaches the system of claim 79. It should be noted that Li fails to teach wherein the expander pin includes fins.
8. Tovey et al. teaches a pin with common fins for insertion into slots (col. 3, lin3s 26-30). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include the fins of Tovey et al. on the expander pin for proper alignment when inserted into the anchor (claim 11).
9. Claims 82-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li.

10. Li teaches the system of claim 70. It should be noted that Li fails to specifically teach that the suture anchor and the expansion pin are made from bioabsorbable material. However, it is well known in the art of suture anchor to use a bioabsorbable material to avoid further surgery after the healing process (as evidenced by US Patents 5814071, 5964783, 6527794, 6660023, 6726707). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a bioabsorbable material including the materials as limited in claims 83 and 85 to allow the body to absorb the material over time so that removal is not needed after healing.

***Double Patenting***

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 70 and 72-85 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8, 11-19, and 22, of U.S. Patent No. 6641596. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims are broader in some respects and adds features in other respects. The structural limitation set forth in

claims 70 and 73-85 of the instant application are also claimed in the patent, e.g., a suture anchor, a bore, a suture engaging tip, an expander pin, an expandable sleeve, threaded regions, bone engaging surface, pin bore, an engaging groove, slits, and bioabsorbable material.

13. As to claim 72, the Patent fails to teach wherein the suture engaging tip is tapered. However, it is well known in the art to taper the tip of an object made for insertion into a bore/hole/cavity for easy alignment and insertion. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to taper the tip for easy insertion into a bore/hole/cavity.

14. Claim 71 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6641596 in view of McDevitt et al. 5814071. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims are broader in some respects and adds features in other respects. The structural limitation set forth in claims 70 and 73-85 of the instant application are also claimed in the patent, e.g., a suture anchor, a bore, a suture engaging tip, an expander pin, an expandable sleeve, threaded regions, bone engaging surface, pin bore, an engaging groove, slits, and bioabsorbable material.

15. The difference between Claim 71 of the instant application and the Claims of the patent is the through-hole extending in a direction transverse to a longitudinal axis.

16. McDevitt et al. teaches a device with a common through-hole for holding a suture. Therefore, it would have been obvious to one having ordinary skill in the art at

the time the invention was made to include the through-hole of McDevitt et al. to hold/retain a suture in place on the anchor (col. 5, lines 17-26).

17. Claim 80 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6641596 in view of Tovey et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims are broader in some respects and adds features in other respects. The structural limitation set forth in claims 70 and 73-85 of the instant application are also claimed in the patent, e.g., a suture anchor, a bore, a suture engaging tip, an expander pin, an expandable sleeve, threaded regions, bone engaging surface, pin bore, an engaging groove, slits, and bioabsorbable material.

18. The difference between claim 80 of the instant application and the Claims of the patent is the fins.

19. Tovey et al. teaches a pin with common fins for insertion into slots (col. 3, lines 26-30). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include the fins of Tovey et al. on the expander pin for proper alignment when inserted into the anchor (claim 11).

***Contacts***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-44963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MM

  
GLENN K. DAWSON  
PRIMARY EXAMINER